IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

NICHOLLE BARCELO, Plaintiff, v. TEVA PHARMACEUTICALS U.S.A., INC., TEVA WOMEN'S HEALTH, INC., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., THE COOPER COMPANIES INC., and COOPERSURGICAL INC. Defendants.	§	CIVIL ACTION NO. 4:20-cv-00017

MEMORANDUM IN SUPPORT OF MOTION FOR JUDGMENT ON THE PLEADINGS BY DEFENDANTS THE COOPER COMPANIES, INC., AND COOPERSURGICAL, INC.

I. INTRODUCTION

This is a personal injury products liability action involving a ParaGard® T380A Intrauterine Copper Contraceptive ("ParaGard IUD"), an FDA-approved drug that is available only by prescription. This Court should dismiss plaintiff's Complaint against CooperSurgical, Inc. ("CooperSurgical") and The Cooper Companies ("Cooper") under Rule 12(c) because plaintiff does not (and cannot) allege either CooperSurgical or Cooper manufactured or sold the ParaGard IUD placed in her. Accordingly, plaintiff's Complaint fails to state a claim against CooperSurgical and Cooper and should be dismissed.

II. BACKGROUND

A. PROCEDURE

Plaintiff filed her Complaint in the Philadelphia County Court of Common Pleas on August 15, 2018, against five Defendants. Defendants timely removed the case to the United States

District Court for the Eastern District of Pennsylvania ("Eastern District"). After denying plaintiff's motion to remand and dismissing two Defendants for being fraudulently joined to defeat diversity jurisdiction[1], the remaining Defendants, Teva Women's Health, Inc. ("TWH, Inc."), Cooper, and CooperSurgical, moved to transfer venue to this Court pursuant to 28 U.S.C. §1404(a). [Doc. No. 21]. In the alternative, Cooper and CooperSurgical moved under Rule 12(c) for judgment on the pleadings for failure to state a claim against them. *Id.*

The Eastern District proceeded on the §1404(a) transfer motion and stayed all other pending motions, including the Rule 12(c) motion filed by Cooper and CooperSurgical. [Doc. No. 24]. After permitting venue discovery, the Court granted the §1404(a) transfer motion on November 18, 2019, and transferred the case to this Court. [Doc. No. 39]. This Court, on February 6, 2020, ordered defendants to file their motion to dismiss by February 21, 2020. [Doc. No. 57].

B. PLAINTIFF'S ALLEGATIONS

Plaintiff alleges she had a ParaGard placed in 2010. [Doc. No. 1, ECF pages 14 – 47] (hereinafter "Complaint" at ¶ 35.) Plaintiff further alleges that when she sought to have the ParaGard removed on or about June 22, 2016, only a portion was removed; one arm of the ParaGard remained embedded. (Complaint ¶¶ 37, 38, 40.) She further alleges that on July 8, 2016, she underwent a hysteroscopy/ablation to remove the remaining embedded arm, but the surgery was unsuccessful. She further alleges that her doctor has advised her to not to remove the remaining arm. (*Id.* ¶ 41.) Plaintiff claims she experienced "pain, suffering, mental anguish, the loss of reproductive health, loss of enjoyment of life, medical expenses and other out of pocket losses and loss of income." (*Id.* ¶ 42.)

[1] Teva Pharmaceuticals USA, Inc., and Teva Branded Pharmaceutical Products R&D, Inc., were dismissed by the Court on March 28, 2019. [Doc. No. 17].

As to Cooper, the only facts alleged by plaintiff are that Cooper "purchased the assets and global rights and business of the ParaGard Intrauterine medical device in November 2017" (*id.*, ¶ 5), well after the alleged placement of plaintiff's ParaGard in 2010, as alleged in plaintiff's Complaint. Plaintiff also alleges CooperSurgical is a subsidiary of Cooper but, consistent with plaintiff's allegations that Cooper and CooperSurgical did not purchase ParaGard assets until November 2017, plaintiff doesn't allege any facts that Cooper or CooperSurgical manufactured or sold the ParaGard IUD allegedly placed in plaintiff in 2010. (*Id.*, ¶¶ 5-6, 8, *see also* Section III. C., *infra*.) Nor can she. Cooper and CooperSurgical agree that they did not manufacture or sell the ParaGard allegedly placed in plaintiff. For example, in her Complaint, plaintiff alleges in different places that "Defendants"[2] manufactured and sold, among others, the ParaGard IUD that was implanted into the plaintiff.[3] Cooper and CooperSurgical specifically denied those allegations. (*See* n.3).

B. PARAGARD'S APPROVAL HISTORY AND LABELING

Although neither CooperSurgical nor Cooper manufactured or sold the ParaGard allegedly placed in plaintiff, it is recognized some background information about ParaGard and its labeling relative to the allegations and claims asserted by plaintiff might be of assistance to the Court in considering and ruling upon this motion. ParaGard is a copper "T" shaped intrauterine device ("IUD") placed in the uterus to prevent pregnancy. The T-frame is made of polyethylene plastic.

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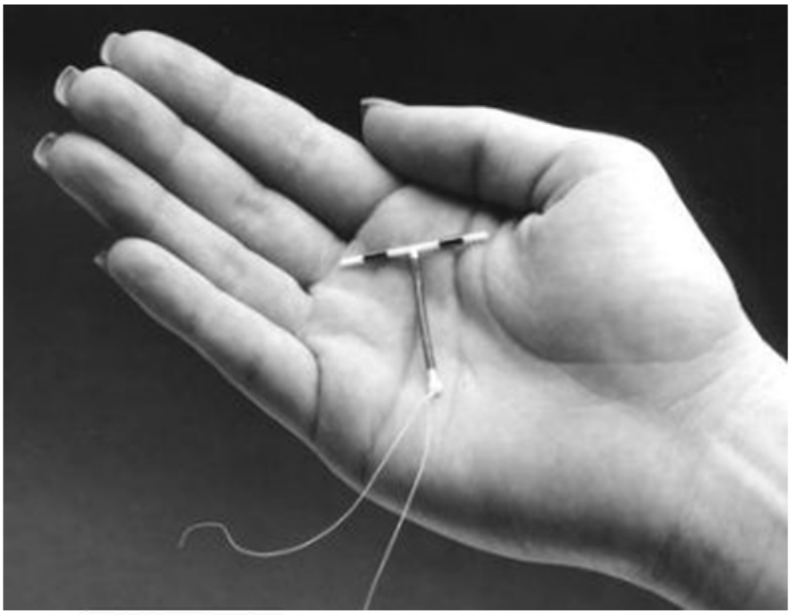
[2] In paragraphs 4 of her Complaint, plaintiff defines the term "Teva Defendants" and uses that term in paragraphs 7 and 12 of her Complaint. Similarly, in paragraph 6, she defines the term "Cooper Defendants" and uses that term only one additional time, in paragraph 8 of her Complaint. In the remainder of her 33 page Complaint, she refers to the "Defendants."

[3] *Compare*, for example, Plaintiff's Complaint at ¶ 49 that "Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the ParaGard IUD that was implanted into the plaintiff"; *with* the Answers filed by Cooper [Doc. 6] and CooperSurgical [Doc. 7], denying those allegations in the corresponding paragraphs.

Approximately 176 mg of copper wire is coiled along the vertical stem and a 68.7 mg collar on each horizontal arm. A ParaGard measures 32 mm horizontally and 36 mm vertically. (ParaGard package insert, available at FDA's website at Drugs@FDA.[4]) A ParaGard is pictured below.



The new drug application ("NDA") for ParaGard was approved by the federal Food and Drug Administration ("FDA") on November 15, 1984. (*See* ParaGard Approval History, available at FDA's website at Drugs@FDA.)

ParaGard's labeling includes a package insert with prescribing information for the physician titled "PRESCRIBING INFORMATION," including detailed diagrams on the proper

[4] The ParaGard package insert is available from FDA's website at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/018680s060lbl.pdf.

The Court may take judicial notice of the ParaGard® package insert as it is a public record. *See Wildman v. Medtronic, Inc.*, 874 F.3d 862, 866 n.2 (5th Cir. 2017) (noting that because the approval process is part of the public record the court is entitled to take judicial notice of the information presented in FDA documents) citing *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (holding that it was appropriate for the court to take judicial notice under Rule 12(b)(6) of documents and transcripts produced by the FDA as "matters of public record directly relevant to the issue at hand."

placement of the IUD, and a patient package insert titled "INFORMATION FOR PATIENTS." (ParaGard package insert.) In addition to a product description, the Prescribing Information describes the mode of action for contraception, indications and usage, instructions for use, and information for patients. The Prescribing Information also includes warnings, contraindications, precautions, and potential adverse reactions to ParaGard®. Under "Warnings," the Prescribing Information lists "embedment":

> 5. **Embedment**
> Partial penetration or embedment of ParaGard® in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.

(*Id.*) Similarly, "Embedment" is disclosed among the "most serious adverse events associated with intrauterine contraception" under the Adverse Reactions section of the package insert. (*Id.*) Under "Continuing Care," the physician is advised that "ParaGard can break" and that it can "perforate the uterus." In the section of the package insert titled "How to Remove ParaGard," the physician again is advised of the risks of embedment and/or breakage:

> Embedment or breakage of ParaGard® in the myometrium can make removal difficult. Analgesia, paracervical anesthesia, and cervical dilation may assist in removing an embedded ParaGard®. An alligator forceps or other grasping instrument may be helpful. Hysteroscopy may also be helpful.

(*Id.*)

Finally, under "Precautions," in a section titled "Information for Patients," the prescribing physician is advised as follows:

> Before inserting ParaGard® discuss the Patient Package Insert with the patient, and give her time to read the information. Discuss any questions she may have concerning ParaGard® as well as other methods of contraception. Instruct her to promptly report symptoms of infection, pregnancy, or missing strings.

(*Id.*) In turn, the "Information for Patients" advises under a section titled "What side effects can I expect with ParaGard®," that there can be "[d]ifficult removals" and "[o]ccasionally ParaGard® may be hard to remove because it is stuck in the uterus. Surgery may sometimes be needed to

remove ParaGard®." (ParaGard information for patients.)

The labeling that was in effect at the time of plaintiff's placement in 2010 was approved by FDA on September 1, 2005. (*See* ParaGard's Approval History at Drugs@FDA.)

III. LAW AND ARGUMENT

A. STANDARD OF REVIEW

A Rule 12(c) motion "is designed to dispose of cases where the material facts are not in dispute and a judgment on the merits can be rendered by looking to the substance of the pleadings and any judicially noticed facts." *Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 312 (5th Cir. 2002). The Rule 12(c) standard for judgment on the pleadings is the same as the standard for a motion to dismiss for failure to state a claim under Rule 12(b)(6). *Gentilello v. Rege*, 627 F.3d 540, 543-44 (5th Cir. 2010). Rule 12(b)(6) allows dismissal if a plaintiff fails "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the United States Supreme Court confirmed that Rule 12(b)(6) must be read in conjunction with Rule 8(a), which requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To withstand a Rule 12(b)(6) motion then, plaintiff's complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570; *see also Elsensohn v. St. Tammany Parish Sheriff's Office*, 530 F.3d 368, 372 (5th Cir. 2008). The Supreme Court has explained that "the pleading standard Rule 8 announces does not require `detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 677.

B. CHOICE OF LAW

"When an action has been transferred from another judicial district pursuant to 28 U.S.C. § 1404(a), the choice-of-law rules of the transferor court apply." *Yelton v. PHI, Inc.*, 669 F.3d

577, 580 (5th Cir. 2012) citing *Ferens v. John Deere Co.*, 494 U.S. 516, 523 (1990) (and noting it was superseded by statute on other grounds). Because the transferor court was located in Pennsylvania, Pennsylvania conflicts of laws apply.

Pennsylvania's choice of law analysis is a hybrid that combines the approach of the Restatement (Second) on Conflicts of Law and the interests of the state analysis. *See Griffith v. United Air Lines, Inc.*, 203 A.2d 796 (Pa. 1964). Pennsylvania's analysis involves a two-prong test. First, the court must determine whether there is a conflict between the states' laws. *See Cipolla v. Shaposka*, 267 A.2d 854, 855 (Pa. 1970)). If there is no conflict, the forum's law applies. *See TIG Specialty Ins. Co. v. Koken*, 855 A.2d 900, 908 n.12 (Pa. Com. Pl. 2004). If a conflict does exist, then the Court must determine which state has the greater interest in applying its law. *See Cipolla*, 267 A.2d at 855-856. The same is true if there is a "false conflict"; i.e., where the result would be the same. *See Titeflex Corp. v. National Union Fire Ins. Co. of Pittsburgh, PA*, 88 A.3d 970, 979 (Pa. Super. 2014)).

There is no conflict here, because both Texas and Pennsylvania law require a plaintiff to identify a manufacturer or seller of the product plaintiff alleges caused her injury in order for liability to attach. *See, e.g., Finnicum v. Wyeth, Inc.*, 708 F. Supp. 2d 616, 619 (E.D. Tex. 2010) (noting that the Texas Supreme Court has "recognized that imposition of products liability is precluded when the defendant did not supply the product that caused the plaintiff's injuries."); *see also Firestone Steel Products Co. v. Barajas*, 927 S.W.2d 608, 614 (Tex. 1996) ("Under traditional products liability law, the plaintiff must prove the defendant supplied the product that caused the injury" citing *Gaulding v. Celotex Corp.*, 772 S.W.2d 66, 68 (Tex. 1989)). *Firestone Steel Products Co.*, 927 S.W.2d at 613 (no duty to warn about the alleged hazards associated with another manufacturer's product).

Under the law of Pennsylvania (where plaintiffs case was originally filed and from where it was transferred), the result is the same. *See Mellon v. Barre-Nat'l Drug Co.*, 636 A.2d 187, 191-92 (Pa. Super. 1993), *appeal denied*, 648 A.2d 789 (Pa. 1994) (holding that absent identification of defendant as manufacturer or seller of product in question "there can be no allegations of duty, breach of duty, or legal causation, and hence there can be no liability.") (Citations omitted); *Long v. Krueger, Inc.*, 686 F. Supp. 514, 517 (E.D. Pa. 1988) ("In a product liability case, the *plaintiff must identify the defendant as the manufacturer or seller of the offending product* before a plaintiff's injuries may be found to be proximately caused by the negligence of the defendant.") (Emphasis added).

C. PLAINTIFF'S COMPLAINT FAILS TO STATE A CLAIM AGAINST COOPERSURGICAL AND COOPER

CooperSurgical and Cooper should be dismissed because plaintiff's Complaint fails to state a cause of action against them. It is elementary that a plaintiff must identify a manufacturer or seller of the product plaintiff alleges caused her injury for liability to attach. *See Finnicum, 708 F. Supp. 2d at 619; Firestone Steel Products Co.*, 927 S.W.2d at 614. But plaintiff did not allege either CooperSurgical or Cooper manufactured or sold the ParaGard IUD placed into her and which she alleges caused her injury. Just the opposite, plaintiff alleges other defendants manufactured and sold the ParaGard IUD. Compare paragraph 7 of plaintiff's Complaint:

> "At all times relevant hereto and alleged herein, the Teva Defendants conducted and continues to regularly conduct substantial business within the Commonwealth of Pennsylvania and within Philadelphia County, which included and continues to include, the research, manufacture, sale, distribution and marketing of the Paragard IUD, which is distributed through the stream of commerce into Pennsylvania and Philadelphia County"

with paragraph 8 of plaintiff's Complaint:

> "At all times relevant hereto and alleged herein, the Cooper Defendants conducted and continues to regularly conduct substantial business within the Commonwealth of Pennsylvania and within Philadelphia County."

(Complaint, ¶¶ 7-8.)

Moreover, Plaintiff alleges she was implanted with her ParaGard IUD in 2010, attempted to have it removed in 2016, and in June, 2017, the decision was made not to remove the retained arm, all of which allegedly caused her to suffer damages. (Complaint, ¶¶ 35, 37-41.) She further alleges "The Cooper Companies purchased the assets and global rights and business of the Paragard Intrauterine medical device in November 2017 for $1.1 Billion, including their manufacturing facility in Buffalo, New York." (*Id.*, ¶ 5.) Plaintiff then alleges CooperSurgical is a subsidiary of Cooper. (*Id.*, ¶ 6.) On the face of plaintiff's Complaint it is clear that CooperSurgical and Cooper did not and could not have manufactured or sold the plaintiff's ParaGard IUD.

Accordingly, liability cannot attach and plaintiff's Complaint fails to state a claim against CooperSurgical or Cooper.

WHEREFORE, Defendants, The Cooper Companies, Inc., and CooperSurgical, Inc., respectfully request an Order from this Court dismissing them from this action.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that February 21, 2020, a true and correct copy of the above and foregoing was e-filed with the Clerk of the Court and served upon all counsel of record by using the CM/ECF system.

/s/ Laura E. De Santos
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